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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/737,197  | 12/16/2003  | Frederic P. Field    | D0188.70170US02     | 5833             |
| 23628   | 7590        | 11/14/2007           | EXAMINER            |                  |
| WOLF GREENFIELD & SACKS, P.C.<br>600 ATLANTIC AVENUE<br>BOSTON, MA 02210-2206 |             |                      | LANG, AMY T         |                  |
| ART UNIT  |             | PAPER NUMBER         |                     |                  |
|   |             | 3731                 |                     |                  |
| MAIL DATE   |             | DELIVERY MODE        |                     |                  |
| 11/14/2007  |             | PAPER                |                     |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/737,197             | FIELD ET AL.        |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | Amy T. Lang            | 3731                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 24 August 2007.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-11, 13-20 and 38-40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-11, 13-20 and 38-40 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

|  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                         | 5) <input type="checkbox"/> Notice of Informal Patent Application                         |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ . | 6) <input type="checkbox"/> Other: _____ .  |

## DETAILED ACTION

### ***Double Patenting***

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. **Claims 1-11, 13-20, and 38-40** are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-22 of copending Application No. 10/396,927. Although the conflicting claims are not identical, they are not patentably distinct from each other because US '927 discloses a suturing instrument comprising an end effector that imparts a looped configuration of the suture when it exits a first channel and enters a second. Therefore, the suture would move away from all portions of the instrument when exiting the first channel in the looped configuration. A wire drive and cutter having multiple faces is also disclosed in the claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

3. **Claims 1-11, 13-20, and 38-40** are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 6,663,643. Although the conflicting claims are not identical, they are not patentably distinct from each other because US '643 discloses a suturing instrument comprising an end effector that imparts a looped configuration of the suture when it exits a first channel and enters a second. Therefore, the suture would move away from all portions of the instrument when exiting the first channel in the looped configuration. A wire drive and cutter having multiple faces is also disclosed in the claims. The cutter bends the suture ends around a fist and second island.

#### ***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

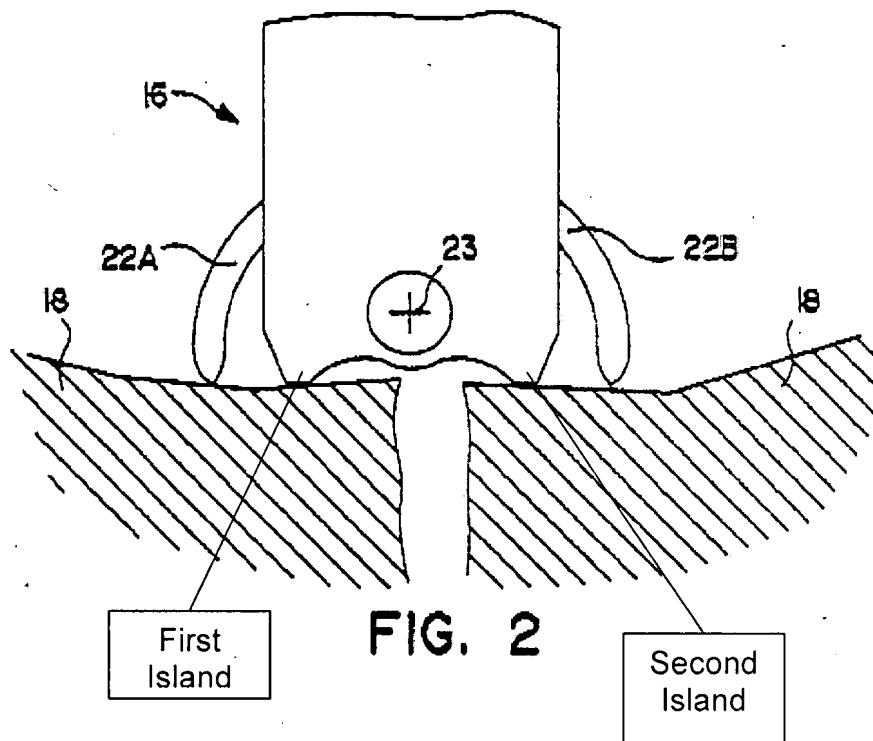
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. **Claims 1-6, 8-11 and 13-18** are rejected under 35 U.S.C. 102(b) as being anticipated by Egan (US 5,417,700).

With regard to **claims 1, 3, and 17**, Egan discloses a suturing instrument (see entire document) comprising a handle (12) and a shaft (13) (Figure 1A). As shown in

Figure 2 and below, the distal portion of the shaft (16) comprises two raised bodies, which clearly overlap the instantly claimed islands. Furthermore, anvil (30) as shown in Figure 4A, also overlaps the instantly claimed island.



As shown in Figure in Figure 5A and below, the instrument further comprises a first channel that guides suture wire toward the opening and a second channel that receives the suture wire. Upon exiting the opening, the suture wire forms a loop. Both the first and second channels comprise a curved flat surface.

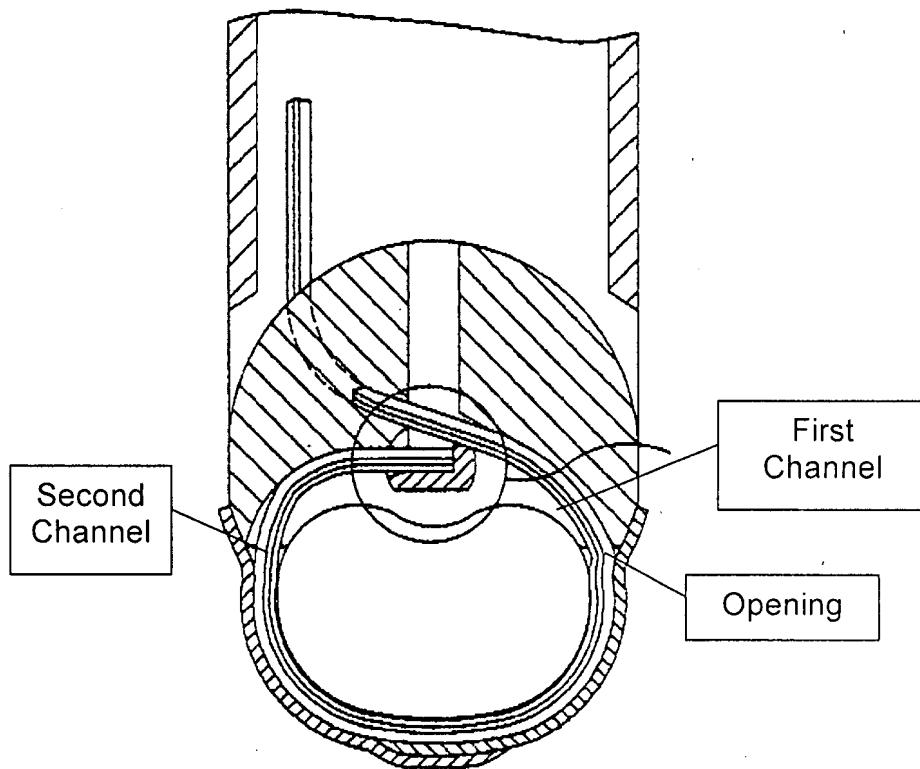


FIG. 5A

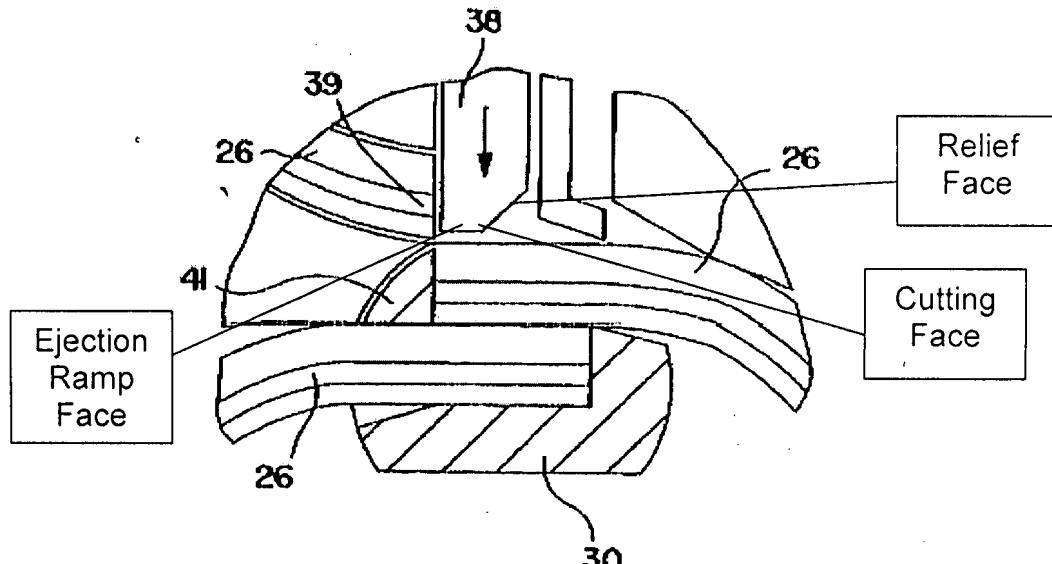
Needle (22) moves the suture material through the tissue to be sutured and therefore overlaps the instantly claimed wire drive (column 5, lines 18-28). Once the suture material forms a loop to close the wound, the two ends of the suture material are welded together (column 6, lines 12-15). Cutter (38) then cuts the suture material to free the suture loop from the rest of the suture material (column 6, lines 16-21). As shown in Figure 10B, the cutter bends each end of the suture loop around one of the islands, the anvil (30). Therefore, the cutter is adapted to bend each end of the wire loop suture around one of the first or second islands.

With regard to **claim 2**, it is the examiner's position that the cutter of Egan is adapted to direct the suture loop away from the first and second channels in a lateral direction as shown in Figure 9B.

With regard to **claim 4**, the space between the first and second projections comprises a recess that is adapted to receive the tissue to be sutured (Figure 2).

With regard to **claims 5 and 6**, the first and second islands comprise projections that are adapted to contact the tissue to be sutured (Figure 2 and 3A).

With regard to **claim 8**, cutter (38) comprises a cutting face, a relief face, and an ejection ramp face as shown below and in Figure 9B. Although Egan does not specifically disclose the relief face as adapted to bend the suture loop around the islands and the ejection ramp face as adapted to direct the suture loop laterally away from the first and second channels, it is the examiner's position that both faces are adapted to meet the claimed embodiments.



**FIG. 9B**

With regard to **claim 9**, is the examiner's position that the cutting face also overlaps the instantly claimed ejection push face since the cutting face pushes the suture loop distally.

With regard to **claims 10 and 11**, Egan teaches that the suturing instrument sutures tissue and the like, which encompasses mesh (column 1, lines 15-22).

With regard to **claim 13**, as shown in Figure 10A, Egan discloses a passageway for cutter (38) disposed between the first and second islands. The distance between the passageway and the islands is greater than the width of suture material.

With regard to **claim 14**, the fist and second channels, as shown in Figure 9A and below, are undercut.

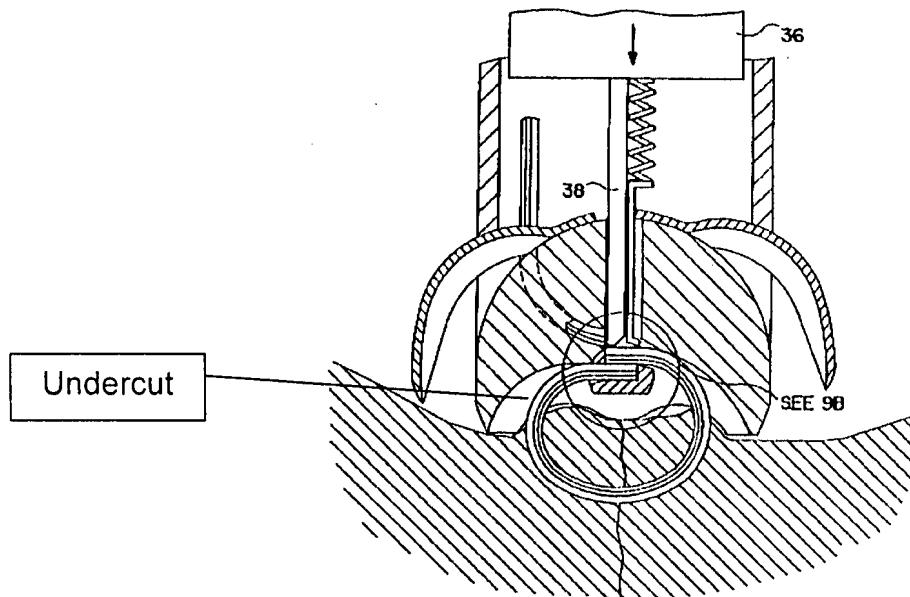


FIG. 9A

With regard to **claim 15**, in one embodiment the wire drive (22) moves the exact amount of suture material so that it is adapted to advance a predetermined length of suture material (column 5, lines 46-48).

With regard to **claim 16**, a multi-function trigger (15) activates the wire drive and the cutter (column 5, lines 1-5).

With regard to **claim 18**, as shown in Figure 9B, the cutter (38) cuts the suture material so that a sharp point is formed on the corner of the cut suture.

#### ***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. **Claims 7 and 19** are rejected under 35 U.S.C. 103(a) as being unpatentable over Egan (US 5,417,700).

Egan discloses a suturing instrument comprising a first and second channel to form a suture loop in tissue. However, Egan does not specifically disclose wherein one island projection is longer than the other and the shaft is detachable.

At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to provide one projection longer and a detachable shaft because Applicant has not disclosed that these limitations provide an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with projections the same size and the shaft as not detachable because the device would still form a suture loop as claimed. Therefore, it would have been an obvious matter of design choice to modify Egan to obtain the invention as specified in the claims.

9. **Claim 20** is rejected under 35 U.S.C. 103(a) as being unpatentable over Egan (US 5,417,700) in view of Meade (US 5,437,681).

Egan discloses a suturing instrument comprising a first and second channel to form a suture loop in tissue. However, Egan does not specifically disclose a suture supply cartridge.

Meade also discloses a suturing instrument wherein the instrument comprises a cartridge containing suture material (column 2, lines 51-53). Therefore it is known in the art to provide a suture supply cartridge so that it would have been obvious to one of ordinary skill at the time of the invention for the suturing device of Egan to also have a suture supply cartridge.

#### ***Terminal Disclaimer***

10. The terminal disclaimers filed on 4/2/2007 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of 10/352,600, 6,511,489, and 7,131,979 has been reviewed and is accepted. The terminal disclaimers have been recorded.

#### ***Allowable Subject Matter***

11. **Claims 38-40 allowed.**

12. The following is a statement of reasons for the indication of allowable subject matter: the prior art of record does not render or teach obvious a suturing instrument

wherein upon exiting a distal channel of the instrument, the suture wire initially moves away from all portions of the instruments and follows a curved path to a second channel in the distal end of the instrument in combination with cutting the suture wire and bending the trailing and leading ends of the cut wire toward a center of the wire loop.

Egan (US 5,417,700) does not disclose a suturing instrument wherein a suture wire, upon existing a first channel in the distal end of the device, moves away from all portions of the device. In the device of Egan, a needle moves the suture wire from the first channel and away from the distal end of the device. Therefore the suture wire is disposed in the needles, a portion of the device, so that it does not move away from all portions of the device when existing the first channel.

### ***Response to Arguments***

Applicant's arguments, filed 8/24/2007, with respect to the prior rejection of Egan have been fully considered and are persuasive. The rejection has been withdrawn. However, the new rejection of Egan presented above overlaps the instant claims.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy T. Lang whose telephone number is 571-272-9057. The examiner can normally be reached on M-F 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

11/9/2007

ATL



Todd E. Manahan  
SPE 3731